1647

CASE D0118 NP

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Stephen C. D'Amico		6-24-04
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

FEDER ET AL.

APPLICATION NO: 10/067,649

FILED: FEBRUARY 5, 2002

FOR: A NOVEL HUMAN G-PROTEIN COUPLED RECEPTOR, HGPRBMY14, RELATED TO THE ORPHAN GPCR, GPR73

Mail Stop DD
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

These references were cited in a search report in a corresponding PCT International application. Copies of these references and the search report are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Certificate under 37 C.F.R. §1.97(e)(1)

I, the undersigned agent, hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.

Respectfully submitted,

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000
(609) 252-5289

Stephen C. D'Amico
Agent for Applicants
Reg. No. 46,652

Date: 6-24-04

FORM PTO-1449 (REV. 7-85)
U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO.
D0118 NP
APPLICATION NO.
10/067,649
APPLICANT
FEDER ET AL.
FILING DATE
FEBRUARY 5, 2002

Group

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	5,891,720	4/6/99	Moore, et al.			
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	AM						☐	☐
	AN						☐	☐
	AO						☐	☐
	AP						☐	☐
	AQ						☐	☐

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	
	AS	
	AT	

EXAMINER | **DATE CONSIDERED**

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

D0118-US-PCT

COR

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

RECEIVED

BMS PATENT LAW

PCT

To:
STEPHEN D'AMICO
BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
ROUTE 206 AND PROVINCELINE ROAD
PRINCETON, NJ 08543-4000

JUN 03 2004

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION
(PCT Rule 44.1)

Docketed Item DS-US-NP-9/1/04
Due Date DS-US-CIP(D0118A) 9-1-04
Attorney DAMICO

Applicant's or agent's file reference D0118	Date of Mailing *(day/month/year)* 01 JUN 2004 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US02/03354	International filing date *(day/month/year)* 05 February 2002 (05.02.2002)
Applicant BRISTOL-MYERS SQUIBB COMPANY	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34, chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90 *bis*.1 and 90 *bis*.3, respectively, before the completion of the technical preparations for international publication.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Jegatheesan Seharaseyon Telephone No. 703-308-0196

Form PCT/ISA/220 (April 2002) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference D0118	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US02/03354	International filing date (*day/month/year*) 05 February 2002 (05.02.2002)	(Earliest) Priority Date (*day/month/year*) 05 February 2001 (05.02.2001)
Applicant BRISTOL-MYERS SQUIBB COMPANY		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
   ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:
   ☒ contained in the international application in written form.
   ☒ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
2. ☒ **Certain claims were found unsearchable** (See Box I).
3. ☒ **Unity of invention is lacking** (See Box II).
4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. ____
   ☐ as suggested by the applicant.
   ☐ because the applicant failed to suggest a figure.
   ☐ because this figure better characterizes the invention.
   ☒ None of the figures

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/03354

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claim Nos.: 20-23,25,26 and 29-32
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
There are multiple claims 20 and 26. Due to numbering problems no meaningful search of claims 21-23 and 25 can be performed. There is no claim 28. Claim 29-32 depends on non existent claim 28.

3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-7, 11 and 12

Remark on Protest
☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/03354

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G01N 33/53; C12Q 1/68; C12P 21/06; C12N 5/00, 15/00; A61K 38/00; C07H 21/04

US CL : 435/6, 7.1, 69.1, 70.1, 320.1, 325; 536/23.1, 23.5; 514/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. 435/6, 7.1, 69.1, 70.1, 320.1, 325; 536/23.1, 23.5; 514/12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

STIC search of SEQ ID NO: 1 and 2, WEST search for HGPRBMY14.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5, 891, 720 A (MOORE et al) 06 April 1999 (6.06.1999), See SEQ ID NO:1 and 2.	1-7, 11 and 12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

15 April 2004 (15.04.2004)

Date of mailing of the international search report

01 JUN 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Jegatheesan Seharaseyon

Telephone No. 703-308-0196

Form PCT/ISA/210 (second sheet) (July 1998)

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. This application also contains several sequences. However, for examination purposes search will be limited to SEQ ID NOs: 1 and 2. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-7, 11 and 12, drawn to the special technical feature of a nucleic acid, an expression vector containing the nucleic acid, a host cell expressing the polypeptide, a cell line transformed with the vector and a method of making the polypeptide and the polypeptide

Group II, claim(s) 8, 9, 13, 19, 24 and 27, drawn to the special technical feature of a polypeptide.

Group III, claim(s) 10, drawn to the special technical feature of an antibody.

Group IV, claim(s) part of 14 , drawn to the special technical feature of a method of preventing, treating or ameliorating a medical condition by administering the polynucleotide of claim 1.

Group V, claim(s) part of 14 , drawn to the special technical feature of a method of preventing, treating or ameliorating a medical condition by administering the polypeptide of claim 8.

Group VI, claim(s) 15, drawn to the special technical feature of a method of diagnosing a pathological condition or susceptibility to a pathological condition based on the presence or absence of a mutation of polynucleotide of claim 1.

Group VII, claim(s) 16, drawn to the special technical feature of a method of diagnosing a pathological condition or susceptibility to a pathological condition based on the presence or amount of polypeptide of claim 8.

Group VIII, claim(s) 17, drawn to the special technical feature of a method for identifying a binding partner to the polypeptide of claim 11.

Group IX, claim(s) 18, drawn to the special technical feature of a method for identifying an activity in a biological assay.

Group X, claim(s) 33, drawn to the special technical feature of a method for treating a disorder related to aberrant NF-kB activity comprising administering an antagonist of the polypeptide of claim 8.

Group XI, claim(s) 34, drawn to the special technical feature of a method for treating a proliferative disorder comprising administering an antagonist of the polypeptide of claim 8.

Group XII, claim(s) 35, drawn to the special technical feature of a method for preventing, treating or ameliorating a medical condition of claim 14, directly linked to aberrant neuropeptide Y receptor activity.

Group XIII, claim(s) 36, drawn to the special technical feature of a method for preventing, treating or ameliorating a medical condition is an eating or appetite disorder.

Group XIV, claim(s) 37, drawn to the special technical feature of a method for preventing, treating or ameliorating a medical condition is a disorder linked to aberrant DNA synthesis.

Group XV, claim(s) 38, drawn to the special technical feature of a method for preventing, treating or ameliorating a medical condition that is a male reproductive disorder.

Group XVI, claim(s) 39, drawn to the special technical feature of a method for preventing, treating or ameliorating a medical condition that is testicular cancer.

The inventions listed as groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons; Claims 1-7, 11 and 12 atleast are anticipated by Moore et al. (U.S. Patent No: 5 891720). Consequently, the special technical feature which links Group I-III, does not provide contribution over the prior art, so the unity of invention is lacking.

Inventions I, II and III are compositions and are different from the methods IV-XVI. The compositions of Inventions I,II and III are different from each other as they are directed to nonequivalent types of compounds with different chemical characters. Invention I is nucleic acid, a cell containing it and a method of making the polypeptide. Invention II is directed to a polypeptide. Invention III is an antibody. Inventions IV-XVII are different from each other as they are directed to nonequivalent methods. Invention IV is a method of of preventing, treating or ameliorating a medical condition by administering the polynucleotide of claim 1. Similarly, Invention V is a a method of preventing, treating or ameliorating a medical condition by administering the polypeptide of claim 8. Invention VI is a method of diagnosing a pathological condition or susceptibility to a pathological condition based on the presence or absence of a mutation of polynucleotide of claim 1. Invention VII is a method for diagnosing a pathological condition or susceptibility to a pathological condition based on the presence or amount of polypeptide of claim 8. Invention VIII is a method for for identifying a binding partner to the polypeptide of claim 11. Invention IX is a method for identifying an activity in a biological assay. Invention X is a method for treating a disorder related to aberrant NF-kB activity comprising administering an antagonist of the polypeptide of claim 8. Invention XI is a method for treating a proliferative disorder comprising administering an antagonist of the polypeptide of claim 8. Invention XII is a method for preventing, treating or ameliorating a medical condition of claim 14, directly linked to aberrant neuropeptide Y receptor activity.
Invention XIII is a method for preventing, treating or ameliorating a medical condition is an eating or appetite disorder. Invention XIV is a method for preventing, treating or ameliorating a medical condition is a disorder linked to aberrant DNA synthesis. Invention XV is a method for preventing, treating or ameliorating a medical condition that is a male reproductive disorder. Invention XVI is a method for preventing, treating or ameliorating a medical condition that is testicular cancer.

The claims of these groups are directed to different inventions, which are not linked to form a single general inventive concept under PCT Rule 13.1. The claims in the different groups lack the same or corresponding special technical features. In particular, each group is directed to different compounds and /or methods. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper.

CHAPTER I
PCT TELEPHONE MEMORANDUM
FOR
LACK OF UNITY OF INVENTION

PCT No.: PCT/US02/03354

Examiner: Jegatheesan Seharaseyon

Attorney spoken to: Stephen D'Amico

Date of call: 06 April 2004

☐ Amount of payment approved:

☐ Deposit account number to be charged:

☐ Attorney elected to pay for ALL additional inventions

☐ Attorney elected to pay only for the additional inventions covered by

☐ Group(s):

-- encompassing –

☐ Claim(s):

☒ Attorney elected NOT to pay for any additional inventions, therefore, only the first claimed invention (Group I) covered by Claim(s) 1-7, 11 and 12 has been searched.

☒ Attorney was orally advised that there is no right to protest for any group not paid for.

☒ Attorney was orally advised that any protest must be filed no later than 15 days from the mailing of the Search Report (PCT/ISA/210).

Time Limit For Filing A Protest

Applicant is hereby given 15 days from the mailing date of this Search Report in which to file a protest of the holding of lack of unity of invention. In accordance with PCT Rule 40.2, applicant may protest the holding of lack of unity only with respect to the group(s) paid for.

Detailed Reasons For Holding Lack of Unity of Invention:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. This application also contains several sequences. However, for examination purposes search will be limited to SEQ ID NOs: 1 and 2. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Note: A copy of this form must be attached to the Search Report.

Group I, claim(s) 1-7, 11 and 12, drawn to the special technical feature of a nucleic acid, an expression vector containing the nucleic acid, a host cell expressing the polypeptide, a cell line transformed with the vector and a method of making the polypeptide and the polypeptide

Group II, claim(s) 8, 9, 13, 19, 24 and 27, drawn to the special technical feature of a polypeptide.

Group III, claim(s) 10, drawn to the special technical feature of an antibody.

Group IV, claim(s) part of 14 , drawn to the special technical feature of a method of preventing, treating or ameliorating a medical condition by administering the polynucleotide of claim 1.

Group V, claim(s) part of 14 , drawn to the special technical feature of a method of preventing, treating or ameliorating a medical condition by administering the polypeptide of claim 8.

Group VI, claim(s) 15, drawn to the special technical feature of a method of diagnosing a pathological condition or susceptibility to a pathological condition based on the presence or absence of a mutation of polynucleotide of claim 1.

Group VII, claim(s) 16, drawn to the special technical feature of a method of diagnosing a pathological condition or susceptibility to a pathological condition based on the presence or amount of polypeptide of claim 8.

Group VIII, claim(s) 17, drawn to the special technical feature of a method for identifying a binding partner to the polypeptide of claim 11.

Group IX, claim(s) 18, drawn to the special technical feature of a method for identifying an activity in a biological assay.

Group X, claim(s) 33, drawn to the special technical feature of a method for treating a disorder related to aberrant NF-kB activity comprising administering an antagonist of the polypeptide of claim 8.

Group XI, claim(s) 34, drawn to the special technical feature of a method for treating a proliferative disorder comprising administering an antagonist of the polypeptide of claim 8.

Group XII, claim(s) 35, drawn to the special technical feature of a method for preventing, treating or ameliorating a medical condition of claim 14, directly linked to aberrant neuropeptide Y receptor activity.

Group XIII, claim(s) 36, drawn to the special technical feature of a method for preventing, treating or ameliorating a medical condition is an eating or appetite disorder.

Group XIV, claim(s) 37, drawn to the special technical feature of a method for preventing, treating or ameliorating a medical condition is a disorder linked to aberrant DNA synthesis.

Group XV, claim(s) 38, drawn to the special technical feature of a method for preventing, treating or ameliorating a medical condition that is a male reproductive disorder.

Group XVI, claim(s) 39, drawn to the special technical feature of a method for preventing, treating or ameliorating a medical condition that is testicular cancer.

The inventions listed as groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons; Claims 1-7, 11 and 12 atleast are anticipated by Moore et al. (U.S. Patent No: 5 891720). Consequently, the special technical feature which links Group I-III, does not provide contribution over the prior art, so the unity of invention is lacking.

Inventions I, II and III are compositions and are different from the methods IV-XVI. The compositions of Inventions I,II and III are different from each other as they are directed to nonequivalent types of compounds with different chemical characters. Invention I is nucleic acid, a cell containing it and a method of making the polypeptide. Invention II is directed to a polypeptide. Invention III is an antibody. Inventions IV-XVII are different from each other as they are directed to nonequivalent methods. Invention IV is a method of of

Note: A copy of this form must be attached to the Search Report.

preventing, treating or ameliorating a medical condition by administering the polynucleotide of claim 1. Similarly, Invention V is a a method of preventing, treating or ameliorating a medical condition by administering the polypeptide of claim 8. Invention VI is a method of diagnosing a pathological condition or susceptibility to a pathological condition based on the presence or absence of a mutation of polynucleotide of claim 1. Invention VII is a method for diagnosing a pathological condition or susceptibility to a pathological condition based on the presence or amount of polypeptide of claim 8. Invention VIII is a method for for identifying a binding partner to the polypeptide of claim 11. Invention IX is a method for identifying an activity in a biological assay. Invention X is a method for treating a disorder related to aberrant NF-kB activity comprising administering an antagonist of the polypeptide of claim 8. Invention XI is a method for treating a proliferative disorder comprising administering an antagonist of the polypeptide of claim 8. Invention XII is a method for preventing, treating or ameliorating a medical condition of claim 14, directly linked to aberrant neuropeptide Y receptor activity. Invention XIII is a method for preventing, treating or ameliorating a medical condition is an eating or appetite disorder. Invention XIV is a method for preventing, treating or ameliorating a medical condition is a disorder linked to aberrant DNA synthesis. Invention XV is a method for preventing, treating or ameliorating a medical condition that is a male reproductive disorder. Invention XVI is a method for preventing, treating or ameliorating a medical condition that is testicular cancer.

The claims of these groups are directed to different inventions, which are not linked to form a single general inventive concept under PCT Rule 13.1. The claims in the different groups lack the same or corresponding special technical features. In particular, each group is directed to different compounds and /or methods. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper.

International application No: PCT/US02/03354

ATTACHMENT TO CHAPTER I PCT TELEPHONE MEMORANDUM FOR LACK OF UNITY OF INVENTION

Note: A copy of this form must be attached to the Search Report.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.